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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/354,450	12/12/94	MICHELSON G	P1093GV

EXAMINER	
HANLON, P	

F3M1/0628

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ART UNIT	PAPER NUMBER
3301	19

DATE MAILED: 06/28/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 19-27 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 19-27 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Specification

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as now claimed. The specification does not provide support for the height of the projection being greater than the largest dimension of the head. There is nothing in the specification which suggests that the distance that the projection extends from the shaft is greater than the diameter of the head. However, the specification does support the limitation that the distance from the top of the projection to the central axis of the shaft is greater than the diameter of the head (said another way, the sum of the radius of the shaft and the height of the projections is greater than the radius of the head). If applicant is attempting to claim the latter limitation, the combined value of shaft radius and projection height, then applicant should amend the claims so that the relationship is clear.

Also, the limitations discussing the spacing of the projections relative to their height is considered new matter. There is nothing in the specification which fairly suggests the relationship that applicant is attempting to claim. The drawings are the only things that could be pointed to for support. However, the drawings do not support applicant's limitations for the distances are not clearly shown in the specification. Also, the drawings can not be used to support such a dimension for applicant's figures are not drawn to scale.

Claim Rejections - 35 USC § 112

2. Claims 19-27 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

3. Claims 19-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is rejected for the confusion regarding the height of the projections relative to the dimensions of the head as discussed in the rejection under the first paragraph of 35 U.S.C. § 112. Claim 21 is also rejected for there is no antecedent basis for "the angle of the tissue and the rivet." Also, it is unclear what applicant is claiming to be

the largest dimension of the head, the diameter, the circumference or the height.

Claim 24 is rejected for what applicant is attempting to claim is unclear. The language of this claim is confusing to the examiner, as is what applicant is trying to claim. Claims 24 and 25 are rejected for where applicant is measuring the apex of the projection from is unclear. Is applicant measuring the apex of the projection from the shaft or the center of the shaft? If applicant is measuring from the center of the shaft, then he is actually measuring the shaft's radius as well as the projections height, and such distances should be reflected in the claims. If applicant is measuring the height from the shaft, then there is no support for such a limitation and the claim is also rejected under the first paragraph of 35 U.S.C. § 112.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102

> of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 19, 22, and 25-27 are rejected under 35 U.S.C. § 103 as being unpatentable over Warren. Warren discloses a surgical rivet. He discloses that the rivet has a hollow shaft and a number of projections extending from said shaft. He also discloses that the rivet is made of a biodegradable material. However, Warren does not discuss the flexibility of its rounded head.

It would have been obvious to modify the rivet of Warren so that its head was flexible enough to conform to the angle of the tissue. This modification would have been obvious for one of ordinary skill would have the rivet in flush contact with the tissue so that a smooth transfer surface would be formed, thereby insuring that nothing would be caught on the extending rivet head and damaged.

6. Claims 20 and 21 are rejected under 35 U.S.C. § 103 as being unpatentable over Warren in view of Bays et al.

Warren discloses the rivet as discussed above. He does not disclose the driver as claimed.

Bays et al (Bays) teach the driver as discussed in the previous office action.

It would have been obvious to modify the rivet of Warren with the driver as taught by Bays. This would have been obvious for Bays teaches that his driving means allows the user to apply the force necessary to correctly place the rivet within the tissue. Applicant is to note that the lengths of his driver's elements are considered to an obvious choices of experimentation and design.

7. Claims 23 and 24 are rejected under 35 U.S.C. § 103 as being unpatentable over Warren in view of Duncan.

Warren discloses the rivet as discussed above. He does not disclose the radially staggered projections as claimed.

Duncan teaches tissue rivets. He discloses that his rivets have radially staggered projections.

It would have been obvious to modify the rivet of Warren with the radially spaced projections as taught by Duncan for Duncan teaches that by staggering the projections, the rivet will be better secured within the body.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Hanlon whose telephone number is (703) 308-2678.

beh
June 25, 1995

ROBERT A. HAFER
S.P.E.
ART UNIT 331